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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/787,840      | 07/06/2001  | Mark Leslie Smythe   | 36677.8             | 8048             |

27683 7590 12/04/2007  
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| EXAMINER |
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KAM, CHIH MIN

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| ART UNIT | PAPER NUMBER |
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1656

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12/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/787,840

Applicant(s)

SMYTHE ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5,7-31,35 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-10,12-31,35 and 39-43 is/are rejected.
- 7) ☒ Claim(s) 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of the Claims*

1. Claims 1-5, 7-31, 35 and 39-43 are pending.

Applicant's amendment filed September 28, 2007 is acknowledged, and applicants' response has been fully considered. Claims 1 and 14 have been amended, and new claims 41-43 have been added. Therefore, claims 1-5, 7-31, 35 and 39-43 are examined.

### **Withdrawn Claim Rejections - 35 U.S.C. § 112**

2. The previous rejection of claims 14, 15 and 35 under 35 U.S.C. § 112, second paragraph, regarding the term "c) on resin cyclization", is withdrawn in view of applicant's response at pages 23-24 in the amendment filed September 28, 2007.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5, 7-10, 12-31, 35 and 39-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claims 1-5, 7-10, 12-31, 35 and 39-40 are indefinite because of the use of term "X is oxygen, sulfur, CH<sub>2</sub>O- or CH<sub>2</sub>S-". The term cited renders the claim indefinite, it is not clear whether the term "CH<sub>2</sub>O- or CH<sub>2</sub>S-" means that the XH group is "CH<sub>2</sub>OH or CH<sub>2</sub>SH" or "CH<sub>3</sub>O- or CH<sub>3</sub>S-" group. Claims 2-5, 7-10, 12, 13, 14-31, 35 and 39-40 are included in the

rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

Response to Arguments

Applicants' response has been fully considered, regarding the term " $R^3$ ,  $R^4$  or  $R^5$  are each ... substituted alkyl, ... substituted aryl, .....substituted arylalkyl,.....substituted heteroaryl, ....", applicant's arguments are found persuasive (pages 22-24 of the response), the rejection is withdrawn. Regarding the term " $CH_2O-$  or  $CH_2S-$ ", Applicant indicate the Specification at page 27 states that the compounds of the present invention comprise a hydroxy or a thiol substituent on the aromatic ring. Thus, the meaning of the terms objected to in claims 1 and 14 is clear, as a skilled artisan would appreciate that in order for the XH substituent to be either a "hydroxy" or a "thiol" moiety. Furthermore, a fair reading of the Specification as a whole by one of skill in the peptide synthetic arts, would *not* lead such a person to interpret the "-XH" moiety as either " $CH_3O-$ " or " $CH_3S-$ ", as suggested on page 3 of the Action, since such an interpretation would *not* result in the presence of an alcohol (*i.e.*, hydroxy;  $-OH$ ) or a thiol (*i.e.*,  $-SH$ ) moiety on the aromatic ring at position 2 or 3, as explicitly set forth in the specification at numerous points therein (see *e.g.*, page 41, para. 2, and page 27, para. 2 in particular). Moreover, none of the exemplary auxiliary compounds listed in Table 1 of the specification recite a " $CH_3O-$ " or " $CH_3S-$ " moiety (page 19-21 of the response).

Applicants' response has been fully considered, however, applicant's arguments are not found persuasive because of the following reasons. While the specification indicates the presence of the alcohol/thiol function at the ortho position of the aromatic ring would increase

the rate of acylation of the substituted amine (see *e.g.*, page 41, para. 2, and page 27, para. 2), the recitation of "X is oxygen, sulfur, CH<sub>2</sub>O- or CH<sub>2</sub>S-" in the claims appears encompassing not only "CH<sub>2</sub>OH or CH<sub>2</sub>SH", but also "CH<sub>3</sub>O- or CH<sub>3</sub>S-" group. Furthermore, none of the exemplary auxiliary compounds listed in Table 1 of the specification recite a "CH<sub>3</sub>O-" or "CH<sub>3</sub>S-" moiety or a "CH<sub>2</sub>OH" or "CH<sub>2</sub>SH" moiety. Maybe use of the term "XH is OH, SH, CH<sub>2</sub>OH or CH<sub>2</sub>SH" would clarify the issue.

5. Claim 23 recites the limitation "General Formula IV" in line 3. There is insufficient antecedent basis for this limitation in the claim, since claim 21, which claim 23 depends from, recites "General Formula III" not "General Formula IV".

6. Claims 41-43 are indefinite because the claims recite "converting the secondary amine to an amide" in both steps (ii) and (iv), it is not clear whether step (ii) is different from step (iv), and how the amide formation would occur in two steps.

#### ***Claim Objections***

7. Claim 11 is objected to because the claims are dependent from a rejected claim.

#### ***Conclusion***

8. Claims 1-5, 7-10, 12-31, 35 and 39-43 are rejected; and claim 11 is objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner



CHIH-MIN KAM  
PRIMARY EXAMINER

CMK

December 3, 2007